

Detailed Instructions for Primary PCI Waiver Application 2006

The application should include the following information. Do not leave any items blank. Enter "0" or "N/A" in items that do not apply.

1. Please provide the following information for each procedure room in the cath lab that was used to perform primary PCI procedures during calendar year (CY) 2004 and CY 2005:

Availability of Cardiac Catheterization Laboratory for Primary PCI Procedures: January 1, 2004 – December 31, 2004

[illegible]

Availability of Cardiac Catheterization Laboratory for Primary PCI Procedures: January 1, 2005 – December 31, 2005

[illegible]

2. Please provide the following information regarding the availability of cath lab team coverage for primary PCI during CY 2004 and CY 2005:

Availability of Cardiac Cath Lab Team for Primary PCI: January 1, 2004 – December 31, 2004

[illegible]

Availability of Cardiac Cath Lab Team for Primary PCI: January 1, 2005 – December 31, 2005

[illegible]

3. Please provide the following information on the current staff to provide cardiac catheterization laboratory services to acute MI patients (as of December 31, 2005):

Total Number of Physician, Nursing, and Technical Staff

Staff	Number	Cross-Training (S/C/M)*
Physician		
Nursing	(FTE)	
Technical	(FTE)	

*Indicate whether the nursing staff and technical staff are cross-trained to scrub (S), circulate (C), and monitor (M).

How many cath lab teams rotate call? _____

On-Call Primary PCI Team Staffing, Rotation, and Response Time

Type of Clinical Staff on Team	Number of Staff	Call Rotation*	Response Time^
MD			
RN			
Technologist:			
Other (specify):			

*Specify the frequency and duration of call (e.g., days/week or month, 1700-0700 hours; weekends/month).

^Specify the time established by the hospital's policy for on-call staff to respond to the call (phone, pager). Response time covers the period from receipt of call to arrival at the hospital.

In addition to listing the physicians who participate in an on-call schedule, please describe the process of scheduling physicians who perform primary PCI for on-call duty.

Does the hospital permit the physicians who participate in the on-call schedule to have simultaneous on-call duties for two or more hospitals?

_____ Yes

_____ No

If yes, what written policies and procedures are in place and followed when the on-call physician is not available or cannot respond?

4. Please provide a breakdown of the number of patients who received PCI after receiving thrombolytic therapy that subsequently failed.

Number of Patients Who Received PCI after Failed Thrombolysis

Number of Patients	
Year 1 – CY 2004	Year 2 – CY 2005

Note: If calendar-year data are unavailable, state why CY data are unavailable and provide data for the most recent 12-month reporting periods (month-day-year).

5. Please provide the following breakdown of patients by door-to-balloon time:

Door-to-Balloon Time	Number of Patients	
	Year 1 – CY 2004	Year 2 – CY 2005
≤ 120 minutes		
> 120 minutes		
<i>Total</i>		

Note: If calendar-year data are unavailable, state why CY data are unavailable and provide data for the most recent 12-month reporting periods (month-day-year).

6. For the discharge period from July 1, 2004 to June 30, 2005, please provide the following data from the QIO Clinical Warehouse, AMI quality measures data set, by submitting a data report from the Delmarva Foundation for Medical Care that contains these data:

- Total number of AMI cases submitted to the warehouse for the specified time period
- Total number of AMI cases submitted to the warehouse where the “Initial ECG Interpretation” question has been answered YES
- Total number of AMI cases submitted to the warehouse where the “Initial ECG Interpretation” question has been answered NO

Note: A written request to Delmarva is required to obtain the data report.

7. Please provide a position description for the physician director of interventional cardiology. Please describe the functions and responsibilities, including responsibility for equipment, personnel, physician call schedules, quality and error management, review conferences, and termination of primary PCI privileges.

8. Please describe the policies and procedures governing the formal, regularly scheduled interventional case review (e.g., determination of need for review, membership of case review team, conduct of case review meeting, minutes/record keeping). Please provide a list of the interventionalists, nurses, and technicians who participate in the formal, regularly scheduled meetings, along with a grid showing dates and attendance from January 1, 2005 through December 31, 2005.

**Interventional Case Review Meetings – Membership and Attendance:
January 1, 2005 through December 31, 2005**

Name and Credential	Title
<i>Physicians</i>	
<i>Nurses</i>	
<i>Technicians</i>	

[illegible]

9. Please provide a list of the participants in the multiple care area group, along with meeting dates and attendance from January 1, 2005 through December 31, 2005.

**Multiple Care Area Group Meetings – Membership and Attendance:
January 1, 2005 through December 31, 2005**

Name and Credential	Title/Care Area
<i>Physicians</i>	
<i>Nurses</i>	
<i>Technicians</i>	

[illegible]

10. Please describe the formal program designed to provide staff working in the cardiac catheterization laboratory (CCL) and staff working in the coronary care unit (CCU) with continuing education pertinent to the area. For staff in each area, identify at least three examples of internal (at the hospital, service, or unit level) or external continuing education during calendar year 2005. If attendance by both staffs is documented, one example may be used to satisfy an educational activity for both.

**Continuing Education Provided to Staff in CCL and CCU:
January 1, 2005 – December 31, 2005**

Type and Topic of Educational Activity	Date	Approved for CEUs*	
		Yes	No

*CEU – continuing education unit of credit. Contact hours of instruction or presentation were in an accredited or approved continuing education course or event.

11. The formal, written agreement with a tertiary institution should be executed by both parties. Please provide a copy of the written agreement signed by authorized representatives of both institutions and specifying that the tertiary institution agrees to receive, on unconditional transfer, patients for any required additional care, including emergent or elective cardiac surgery or PCI, from the hospital performing primary PCI without on-site cardiac surgery.

12. The formal, written agreement with an advanced cardiac life support emergency medical services provider should be executed by both parties. Please provide a copy of the written agreement signed by authorized representatives and specifying that the advanced cardiac life support emergency medical services provider guarantees arrival of the air or ground ambulance within 30 minutes of a request for patient transport by the hospital performing primary PCI without on-site cardiac surgery. Use of the term “response” must clarify that response time covers the period from receipt of call by the EMS provider to arrival at the requesting hospital.

13. Please provide the following breakdown of the total number of procedures of each interventional cardiologist with privileges to perform primary PCI at the applicant hospital:

Number of PCI Cases by Physician, Institution, and Year

Physician	Number of PCI Cases					
	Year 1:			Year 2:		
	Applicant	Other	Total	Applicant	Other	Total

14. Please confirm that any physician identified as newly out of fellowship (less than three years) fulfilled the minimum volume requirements (described below) before being allowed to perform primary PCI alone at the hospital, and indicate the actual number of fellowship or proctored cases performed.

Physicians newly out of fellowship (less than three years) should have completed a minimum of 50 acute MIs during their fellowship training or 10 proctored cases before being allowed to perform primary PCI alone.

15. Please confirm that each physician listed as having privileges to perform primary PCI has met the credentialing criteria for the institution, identifying the date(s) when each physician met the credentialing criteria.

16. Please provide the following information for STEMI patients who presented to the hospital and died or were transferred to another acute care hospital during CY 2004 and CY 2005:

**Number of STEMI Patients Who Died or Were Transferred to Acute Care Hospital:
CY 2004 and CY 2005**

Patient Disposition	Number of STEMI Patients	
	CY 2004	CY 2005
In-hospital death		
Transfer to other acute care hospital (reason):		
> 50% left main stenosis		
High risk coronary anatomy ¹		
Could not identify IRA ²		
Cath lab not available		
Staff not available (MD, RN, Tech)		
Other (specify):		
<i>Total transfers</i>		

¹For example, severe triple-vessel coronary artery disease

²IRA – Infarct-related artery

Note: If calendar-year data are unavailable, state why CY data are unavailable and provide data for the most recent 12-month reporting periods (month-day-year).